

## Message Text

UNCLASSIFIED

PAGE 01 MEXICO 03485 260215Z

64

ACTION HEW-08

INFO OCT-01 ARA-16 ISO-00 SCI-06 EB-11 DRC-01 RSC-01 /044 W

----- 068881

R 252353Z APR 74

FM AMEMBASSY MEXICO

TO SECSTATE WASHDC 1366

UNCLAS MEXICO 3485

E.O. 11652: N/A

TAGS: TBIO-MX

SUBJ: RECALL OF DISPOSABLE BLOOD OXYGENATORS

REF: STATE A-3173

PASS TO HEW, FOOD AND DRUG ADMINISTRATION

1. CONSIDERING SUBSTANTIAL TIME LAPSE BETWEEN MANUFACTURER NOTIFICATION OF DEFECT AND FDA RECALL OF BLOOD OXYGENATORS, EMBASSY CONTACTED THE ONLY DISTRIBUTOR IN MEXICO, HARRY MAZAL, S.A. TO LEARN WHETHER OXYGENATORS ALREADY USED. MAZAL CONFIRMED IN PHONE CALL AND FOLLOW-UP LETTER THAT ALL OXYGENATORS HAVE ALREADY BEEN CORRECTED AND USED. HE SENT EMBASSY COPIES OF LETTERS FROM MANUFACTURER, BENTLEY LAB, DATED FEBRUARY 11 NOTIFYING OF THE DEFECT AND CORRECTION PROCEDURE. MAZAL AFFIRMS IN COVERING LETTER HE SENT BENTLEY LETTER TO ALL USERS AND HIS OWN STAFF PERFUSIONIST DEMONSTRATED PROPER CONNECTIONS TO EACH USER. HE STATED OXYGENATOR USED WITHOUT MISHAPS SINCE BENTLEY PROVIDED INFORMATION BEFORE PRODUCTS SOLD.

2. IN VIEW OF ABOVE, EMBASSY DOES NOT WISH PRESS MATTER FURTHER. INVOLVEMENT OF MEXICAN GOVERNMENT WILL NOT CHANGE SITUATION AND MAY ONLY COMPLICATE BUSINESS DEALINGS FOR THE MEXICAN DISTRIBUTOR WHO HAS ALREADY DONE ALL HE COULD. PLEASE ADVISE IF FURTHER ACTION NECESSARY.

JOVA

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NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** SAFETY, MEDICAL FACILITIES  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 25 APR 1974  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1974MEXICO03485  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** n/a  
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**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D740098-0836  
**From:** MEXICO  
**Handling Restrictions:** n/a  
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**Line Count:** 51  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ACTION HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
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**Previous Handling Restrictions:** n/a  
**Reference:** STATE A-3173  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** shawdg  
**Review Comment:** n/a  
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**Review Date:** 15 OCT 2002  
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**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** RECALL OF DISPOSABLE BLOOD OXYGENATORS  
**TAGS:** TBIO, MX  
**To:** STATE  
**Type:** TE  
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